

Patent
030727.0035.UTL1**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**Applicants: Erion *et al.*

Serial No.: 09/657,919

Filed: September 8, 2000

Title: **PRODRUGS FOR LIVER SPECIFIC
DRUG DELIVERY**

Group Art Unit: -1623

Examiner: J.O. Wilson

Commissioner for Patents
Washington, D.C. 20231**PETITION FOR EXTENSION OF TIME
&
AMENDMENT AND RESPONSE**

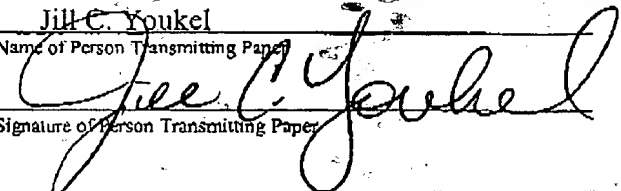
Dear Sir:

This communication is in response to the Office Action mailed on September 16, 2002.

Applicants hereby petition for a three-month extension of time in which to respond to the Office Action mailed on September 16, 2002. With the granting of the foregoing Petition, the time for responding to this Office Action is extended to include March 17, 2003, because March 16, 2003, falls on a Sunday. The Commissioner is hereby authorized to charge trust account No. 50-2613 for the three-month extension fee due herein, and any other fees that may become due or credit become payable during the pendency of this application.

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comments:

Re: U.S. Patent Application Ser. No.: 09/657,919
Filed 09/08/2000
PRODRUGS FOR LIVER SPECIFIC DRUG DELIVERY
Our Ref: 030737.0035.UTL

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GROUP 1600**OFFICIAL**

Please see attached, our Response to Office Action mailed 9/20/2002.

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Response to Restriction Requirement
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AMENDMENTS

In the claims:

Please cancel claims 50-64, 89-103, and 119-154 without prejudice. The Applicants reserve the right to pursue claims to non-elected inventions in a Divisional application.

In the specification:

Please amend the paragraph at p. 34, lines 6-15 to read:

Various kinds of parent drugs can benefit from the prodrug methodology of the present invention. It is preferred that the prodrug phosph(oramid)ate moiety be attached to a hydroxy, amine, or thiol on the parent drug. In many cases the parent drug will have many such functional groups. The preferred group selected for attachment of the prodrug is the group that is most important for biological activity and is chemically suitable for attachment of the prodrug moiety. Thus, the phosph(oramid)ate moiety will prevent the prodrug from having biological activity. An inactive prodrug should limit systemic side effects because higher drug concentrations will be in the target organ (liver) relative to non-hepatic tissues. The amine should have at least one N-H bond, and preferably two.

REMARKS

Claims 1-158 are pending. The Examiner has withdrawn claims 50-64, 89-103, and 119-154 from consideration as directed to non-elected inventions. Claims 1-49, 65-88, 104-118, and 155-158 stand rejected.

The Applicants respectfully note that claims 1-49, 65-88, 104-118, and 155-158 are the correct claims and not claims 1-49, 65-87, 104-118, and 155-158, as indicated by the Examiner on the Office Action Summary Page. The Examiner has used the correct numbers in rest of the Office Action.

The amendment to the specification was merely to correct a typographical error and does not constitute new matter.

I. JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

Claims 1-49, 65-88, 104-118, and 155-158 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 95-97, 99-172, and 174 of the Erion *et al.* patent, U.S. Patent No. 6,312,662. The Examiner says: